IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
_____Division

LIFENET HEALTH, a Virginia Corporation, Plaintiff, v. TISSUE REGENIX WOUNDCARE INC., a Delaware Corporation and COMMUNITY TISSUE SERVICES, an Ohio Corporation, Defendants.	Civil Action No. **JURY TRIAL DEMANDED**

COMPLAINT

LifeNet Health ("LifeNet"), by and through its undersigned counsel, states as follows for its complaint against the defendants, Tissue Regenix Woundcare Inc. ("Tissue Regenix") and Community Tissue Services (collectively, "Defendants"):

THE PARTIES

LifeNet Health

1. LifeNet is a nonprofit corporation organized under 26 U.S.C. § 501(c)(3) and existing under the laws of the Commonwealth of Virginia and having a principal place of business in this judicial district at 1864 Concert Drive, Virginia Beach, Virginia 23453.

2. LifeNet's mission statement is "Saving Lives, Restoring Health and Giving Hope." Founded in 1982 as the Eastern Virginia Tissue Bank, LifeNet is one of the world's most trusted providers of transplant solutions, from organ and tissue procurement to innovative

bio-implant technologies and cellular therapies.

3. Each year, LifeNet facilitates the transplantation of over 400 organs in the United States and distributes over 500,000 allograft bio-implants to meet the needs of hospitals and patients in the United States. An allograft is human donor tissue, such as skin, bone, tendon, and cardiovascular tissue, intended for transplantation in a human recipient.

4. LifeNet is also extensively involved in promoting and facilitating tissue-donation and bio-implant tissues. For example, LifeNet's Tissue Services Division is dedicated to training, educating, and maintaining relationships with more than 50 partners to promote tissue donation in their respective communities.

5. LifeNet also established its Plastic & Reconstructive Surgical Specialties franchise to ensure the processing and delivery of skin/dermal allograft bio-implants for U.S. trauma and burn centers.

6. In addition, LifeNet's Bio-Implants Division has pioneered technologies related to all aspects of the allograft bio-implant production process, including disinfection, decellularization (*i.e.*, the removal of cellular elements from an allograft bio-implant), preservation, and sterilization.

7. LifeNet is also a member of several organizations related to tissue donation. For example, LifeNet is an accredited member of the American Association of Tissue Banks, and also a member organization of Donate Life America, a not-for-profit alliance of national organizations across the United States committed to increasing organ, eye, and tissue donation.

8. The patent asserted by LifeNet in this Complaint is a result of LifeNet's extensive research and development in the field of tissue and bio-implant technology.

Tissue Regenix

9. Upon information and belief, Tissue Regenix is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 2611 North Loop 1604 West, Suite 201, San Antonio, Texas 78258.

10. Tissue Regenix is in the business of manufacturing, using, selling, and/or offering for sale various medical products, including skin/dermal products under the brand names DermaPure® Decellularized Dermal Allograft and SurgiPure™ XD Reconstructive Tissue Matrix.

11. Upon information and belief, DermaPure® Decellularized Dermal Allograft is human dermal allograft, and SurgiPure™ XD Reconstructive Tissue Matrix is porcine (pig) skin xenograft.

Community Tissue Services

12. Upon information and belief, Community Tissue Services is a not-for-profit corporation organized under 26 U.S.C. § 501(c)(3), existing under the laws of the State of Ohio, and has a principal place of business at 33 West First Street, Suite 600, Dayton, Ohio 45402.

13. Community Tissue Services is in the business of manufacturing, using, selling, and/or offering for sale various medical products including skin/dermal products under the brand names DermaPure® Decellularized Dermal Allograft and SurgiPure™ XD Reconstructive Tissue Matrix.

JURISDICTION AND VENUE

14. This action is a claim for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 271, *et seq*.

15. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1332, and 1338(a).

16. This Court has personal jurisdiction over Tissue Regenix and Community Tissue Services at least because Tissue Regenix and Community Tissue Services have substantial, continuing, and on-going contacts within the Commonwealth of Virginia and this judicial district, and Tissue Regenix and Community Tissue Services have sold and continue to sell products at issue in this case in this Commonwealth and judicial district.

17. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and 1400(b) in that acts of patent infringement have occurred and are occurring within this judicial district.

FACTS

U.S. Patent No. 6,569,200

18. On June 5, 2001 , Lloyd Wolfinbarger, Jr., Robert K. O'Leary, and Billy G. Anderson (collectively, "the Inventors"), filed U.S. Patent Application No. 09/874,862 ("the '862 Application"). The '862 Application is a division of U.S. Patent Application No. 09/107,459, filed June 30, 1998, now U.S. Patent No. 6,293,970.

19. On August 29, 2002 the '862 application published as U.S. Publication No. 2002/0120345. On May 27, 2003, the U.S. Patent and Trademark Office ("USPTO") issued the '862 application as U.S. Patent No. 6,569,200 ("the '200 Patent"). A copy of the '200 Patent is attached as **Exhibit A**.

20. LifeNet is the assignee of all right, title, and interest in and to the '200 Patent and possesses all rights of recovery under the '200 Patent.

21. The '200 Patent is directed to, *inter alia*, "plasticized dehydrated or freeze-dried bone and/or soft tissue product[s] that do[] not require special conditions of storage," and methods for producing the same. *See* Exhibit A, '200 Patent Abstract.

22. In 2007, LifeNet introduced Preservon® technology, its proprietary bio-implant tissue-preservation technology based on the '200 Patent family. It is an ambient temperature (room temperature) preservation method that simplifies the tissue-preparation and product distribution processes and storage, saves valuable time in the operating room, and allows allograft tissue to retain its physical and biomechanical properties.

23. Starting in 2010 with the launch of its Oracell® dermal implant, LifeNet has marked its products incorporating the Preservon® technology with the '200 Patent number.

24. In September 2013, LifeNet filed suit in this Court asserting infringement of the '200 Patent against LifeCell Corporation. *See* D.I. 1, Civil Action No. 2:13-cv-00486, September 6, 2013 (E.D. Va.).

25. After a ten-day trial, the jury found that the '200 Patent was valid and infringed by LifeCell's allograft and xenograft tissue products sold under the brand names AlloDerm® RTM Ready to Use, Strattice™ Reconstructive Tissue Matrix, GraftJacket® Regenerative Tissue Matrix, and Conexa™ Reconstructive Tissue Matrix. *See id.*, D.I. 369. The Court of Appeals for the Federal Circuit upheld the claims on appeal. *See LifeNet Health v. LifeCell Corp.*, 837 F.3d 1316 (Fed. Cir. 2016).

Defendants' Infringing Products

26. Upon information and belief, Defendants have been manufacturing, using, selling, and offering for sale a tissue product under the brand name DermaPure® Decellularized Dermal Allograft ("DermaPure").

27. Defendants market DermaPure as a Human Cells, Tissues, and Cellular and Tissue-Based Product ("HCT/P"). Under 21 C.F.R. § 1271.10(a), HCT/Ps need not be approved by the U.S. Food and Drug Administration ("FDA") if, among other requirements, they are

minimally manipulated and intended solely for homologous use.

28. Defendants make the following claims about DermaPure:

- "DermaPure is a new decellularized human dermis product from Tissue Regenix. The product concept replaces human dermis with human dermis, to most closely approximate the structure and function of the native tissue it is replacing." Community Tissue Services Allograft Offerings Brochure (attached as **Exhibit B**), page 26.

- "DermaPure is produced using dCELL Technology. The proprietary process maintains the essential structure of the native extracellular matrix, and preserves a high degree of the natural tissue's biomechanical properties . . ." DermaPure Product Page, Tissue Regenix Woundcare Inc., (attached as **Exhibit C**).

- "DermaPure requires no thawing, no rehydrating, no special storage." *Id.*

- "DermaPure is stored at ambient temperature and comes hydrated, with only a simple rinse required prior to use." *Id.*

29. Upon information and belief, DermaPure is a plasticized soft tissue graft, as set forth in at least claims 1-3, 7, and 8 of the '200 Patent. *See*, *e.g.*, Exhibit B, page 26; Exhibit C; Tissue Regenix Group Corporate Overview Presentation (June 7, 2016) (attached as **Exhibit D**), page 14; Tissue Regenix Website, dCell Technology (attached as **Exhibit E**).

30. Upon information and belief, DermaPure is suitable for transplantation into a human, as set forth in claims 1-3, 7, and 8 of the '200 Patent. *See*, *e.g.*, Exhibit C; Exhibit D, pages 14-16; DermaPure Instructions for Use QC-605-F-24-Rev 03 (attached as **Exhibit F**); June 4, 2015.

31. Upon information and belief, DermaPure is a cleaned soft tissue graft, as set forth in claims 1-3, 7, and 8 of the '200 Patent. *See*, *e.g.*, Exhibits B, C, D, E, F.

32. Upon information and belief, DermaPure has an internal matrix, as set forth in claims 1-3, 7, and 8 of the '200 Patent. *See*, *e.g.*,*id*.

33. Upon information and belief, DermaPure has one or more plasticizers contained

in the internal matrix, as set forth in claims 1-3, 7, and 8 of the ’200 Patent. *See*, *e.g.*, Exhibit B, page 27; Exhibits C – F.

34. Upon information and belief, in DermaPure one or more plasticizers are not removed from the internal matrix of the plasticized soft tissue graft prior to transplantation into a human, as set forth in claims 1-3, 7, and 8 of the ’200 Patent. *See*, *e.g.*, Exhibit F.

35. Upon information and belief, Defendants have been manufacturing, using, and preparing to commercialize a tissue product under the brand name SurgiPure™ XD Reconstructive Tissue Matrix (“SurgiPure”).

36. Defendants obtained marketing clearance for SurgiPure through FDA’s substantial equivalence pathway for medical devices, Section 510(k) of the Food, Drug, and Cosmetic Act (“FDCA”). *See* SurgiPure 510(k) Clearance letter, Mar. 8, 2016 (attached as **Exhibit G**)

37. Defendants represented to the FDA that SurgiPure is substantially equivalent to LifeCell Corporation’s Strattice™ Reconstructive Tissue Matrix (LTM Surgical Mesh, K070560) (“Strattice”). In doing so, Defendants represented that SurgiPure has the same intended uses and the same or similar indications, technological characteristics and principles of operation as Strattice and Defendants have performance data that demonstrates that SurgiPure functions equivalently to Strattice. *See id*.

38. Upon information and belief, SurgiPure is substantially equivalent to Strattice, a product already found to infringe the ’200 Patent.

39. Upon information and belief, SurgiPure is a plasticized soft tissue graft, as set forth in at least claims 1-3, 7, and 8 of the ’200 Patent. *See*, *e.g.*, *id.*

40. Upon information and belief, SurgiPure is suitable for transplantation into a human, as set forth in claims 1-3, 7, and 8 of the ’200 Patent. *See*, *e.g.*, *id*.

41. Upon information and belief, SurgiPure is a cleaned soft tissue graft, as set forth in claims 1-3, 7, and 8 of the ’200 Patent. *See*, *e.g.*, Exhibits E and G.

42. Upon information and belief, SurgiPure has an internal matrix, as set forth in claims 1-3, 7, and 8 of the ’200 Patent. *See*, *e.g.*, Exhibits D, E, and G.

43. Upon information and belief, SurgiPure has one or more plasticizers contained in the internal matrix, as set forth in claims 1-3, 7, and 8 of the ’200 Patent. *See*, *e.g.,* Exhibit G.

44. Upon information and belief, in SurgiPure, one or more plasticizers are not removed from the internal matrix of the plasticized soft tissue graft prior to transplantation into a human, as set forth in claims 1-3, 7, and 8 of the ’200 Patent. *See*, *e.g.*, Exhibits G.

45. Defendants have sold and offered for sale, and continue to sell and offer for sale DermaPure and SurgiPure (collectively, the “Infringing Products”) in this Commonwealth and this District, including but not limited to hospitals and other surgical centers.

COUNT I

INFRINGEMENT OF THE ’200 PATENT

46. Plaintiff LifeNet realleges and incorporates by reference paragraphs 1 through 45 of this Complaint as though fully set forth herein.

47. Defendants Tissue Regenix and Community Tissue Services have infringed and continue to infringe, either directly or by equivalents, at least claims 1-3, 7, and 8 of the ’200 Patent by, without LifeNet’s authority, manufacturing, causing to be manufactured, using, offering for sale, and/or selling in the United States at least the Infringing Products, pursuant to 35 U.S.C. § 271(a).

48. LifeNet has suffered monetary damages by reason of Defendants' Tissue Regenix and Community Tissue Services infringement of the '200 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff LifeNet requests relief against Defendants Tissue Regenix and Community Tissue Services as follows:

(a) A judgment that Defendants have directly infringed the '200 Patent;

(b) A judgment and order requiring Defendants to pay damages under 35 U.S.C. § 284, together with costs and prejudgment and post-judgment interest;

(c) A finding that this case is an exceptional case, and an order awarding Plaintiff its costs and reasonable attorney fees under 35 U.S.C. § 285; and

(d) Any and all such other and further relief as the Court may deem appropriate.

JURY DEMAND

LifeNet hereby demands a trial by jury on all issues triable to a jury.

Dated: May 8, 2017

Respectfully submitted,

/s/ Stephen E. Noona

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